

AUG 26 2002

K022530

510(k) SUMMARY

Submitted For: **HYCARE INTERNATIONAL CO., LTD.**
457/2 Moo 3, Airport Road, Hat-Yai
Songkhla, 90110, Thailand

Submitted By: **TUCKER & ASSOCIATES**
Official Correspondent for Hycare International Co., Ltd.
JANNA P. TUCKER, President-CEO
198 Avenue de la D'emerald
Sparks, NV 89434-9550
Phone: 775-342-2612
Fax: 775-342-2613
E-Mail: Tuckerjan@aol.com

Date of Submission: 29 July 2002

Device Name: **POWDERED LATEX EXAM GLOVES,**
WITH PROTEIN LABELING (200 ug/g or less)
Class I Device, 80LYY

Proprietary Name: (Multiple Labels) Powdered Latex Exam Gloves,
With Protein Labeling (200 ug/g or less)

Labels/Labeling: This device will be marketed to healthcare professionals at
Dentist and Doctor Offices, Laboratories, Clinics and
Hospitals through its distributors for the intended use.

Intended Use: A patient examination glove is a disposable device intended
for medical purposes that is worn on the examiner's hand
or finger to prevent contamination between patient and
examiner.

Substantial Equivalence: Both in its intended use and/or physical
characteristics, this device is equivalent to devices
currently marketed by U.S. companies. It is **Substantially**
Equivalent to the devices manufactured by Premier
Pathway **K001327**, and SGMP Company Ltd. **K000390**.

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Test Results (Means
and/or Successful
Results:

This device has met or exceeded the following
standards and/or tests:

ASTM D 5712-99
ASTM D 3578-01
ASTM D 6124-99
ASTM D 5151-99
ISO 2859

Bio-Compatibility:
Dermal Sensitization
Primary Skin Irritation

Conclusion:

This device is substantially equivalent to the devices
approved as K001327 and K000390.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Hycare International Company, Limited
C/O Ms. Janna P. Tucker
Official Correspondent for Hycare International Company, Limited
Tucker and Associates
198 Avenue De La D' emerald
Sparks, Nevada 89434-9550

Re: K022530
Trade/Device Name: Powdered Latex Exam Gloves with Protein Labeling 200
Microgram or Less of Total Water Extractable Protein Per Gram
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: July 29, 2002
Received: July 31, 2002

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: HYCARE INTERNATIONAL, CO., LTD

510(k) NUMBER: K022530

DEVICE NAME: POWDERED LATEX EXAM GLOVES,
WITH PROTEIN LABELING (200 ug/g
or less) of Total Water Extractable Protein per gva

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)

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Chin S. Lim
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
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